

IVD MANUFACTURER QUESTIONNAIRE
PLEASE PRINT

FIRM NAME: _____

ADDRESS: _____

CENTRAL FILE NUMBER: _____

FDA DISTRICT OFFICE: _____

1. Does the firm use human blood and/or blood products in the manufacture of the IVD(s)?

_____ NO _____ YES (If "NO", questionnaire is complete)

2. Are human blood and/or blood products **imported** for incorporation into the IVD(s)?

_____ NO _____ YES

If yes, list the foreign countries where the products were collected and provide the name(s) and address(es) of the foreign establishment(s).

3. Are human blood and/or blood products obtained from a broker for incorporation into the IVD(s)?

_____ NO _____ YES

If yes, list the name(s) and address(es) of the broker(s).

4. If question 2 and/or 3 above is answered "yes", please complete page 2 of this form.